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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,174	10/20/2003	Roger Strickland	2979	2714

7590 12/07/2004

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EXAMINER

MITCHELL, TEENA KAY

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 12/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/689,174

Applicant(s)

STRICKLAND ET AL.

Examiner

Teena Mitchell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Priority

It is noted that this application appears to claim subject matter disclosed in prior Application No. 10/042,042, filed 10/25/01. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of

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any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

While the examiner has reviewed all references listed in application 10/042,042 and listed on patent 6,679,265, should applicant want such references listed on any patent that may issue from the instant application, applicant must submit the appropriate 1449 form (note MPEP 609).

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 5 has been renumbered 4.

Misnumbered claim 6 has been renumbered 5.

Misnumbered claim 9 has been renumbered 6.

Because this application is a new application the claims need to be numbered accordingly (i.e., 1-6).

Also in claim 5, line 1, "...The nasal cannula of claim 5..." needs to be amended to read --The nasal cannula of claim 4-- because the claims have been renumbered; therefore the claim dependency has changed. Correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Wood (6,807,967).

Wood in a nasal cannula (10) for use with a positive air pressure system (Col. 5, lines 54-67 and Col. 6, lines 1-20) providing a flow F to the cannula, said nasal cannula comprising first and second nasal inserts (22, 30) for insertion into a patient's nares (Fig. 1), whereby the area of each insert and the area of the nare are essentially equal so that positive air pressure seal is created between the nare and the insert (Col. 6, lines 30-67 and Col. 7, lines 1-35); a left delivery tube and a right delivery tube (18), each coupled to both of said nasal inserts (Fig. 2A), whereby each nasal insert communicates with both the left delivery tube and right delivery tube; a coupler (12) located remote from said nasal inserts (22) for coupling said cannula to said source of respiration gas; at least one bleed port (38) positioned proximate a nasal insert communicating with said delivery tubes, directly open to atmospheric pressure (Figs. 2A, 4).

With respect to claim 2, Wood discloses two tubular bleed ports (Fig. 2A) each having an internal lumen (Fig. 4, 38); each of said tubular bleed ports (38) located directly in line with one of said nasal insert (Fig. 2A) for preferentially intercepting expired gas during an exhalation, said bleed port having an characteristic bleed port diameter (Fig. 4), and separated by a distance (Fig. 2A, Col. 6, lines 59-67 and Col. 7, lines 1-54).

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With respect to claim 4, Wood discloses wherein said nasal inserts (22, 30) terminate in a compliant flange (36) at their distal ends to conform to the nare of a patient.

With respect to claim 5, Wood discloses wherein each of said first or second nasal inserts (22, 30) has a characteristic length (Fig. 2A); the length of either the first or second nasal insert are sufficiently long to allow an insert to move in the nasal passage until the cross section area of the nare and the cross section of said nasal insert, are substantially the same, thereby forming a positive pressure seal between said nasal insert and said nare (Col. 6, lines 30-67 and Col. 7, lines 1-54).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wood (6,807,967).

The difference between Wood and claim 3 is Wood is not specific on the amount of carbon dioxide content of inspired air to a value below approximately 0.5% carbon dioxide for the air inhaled from and retained by the delivery tubes. However, Wood does disclose that the internal diameter of the bleeder port is ample to permit venting of carbon dioxide exhaled by the patient while not being so large as to cause a significant pressure drop in the cannula body (Col. 7, lines 14-34). Based on the size of the bleeder ports one of ordinary skill in the art would be able to arrive at a specific value of below 5% carbon dioxide for the air inhaled and retained by the delivery tubes, as in the respiratory field it is always a concern of retention of CO₂.

With respect to claim 6, note rejection of claims 1, 3, and 4 above.

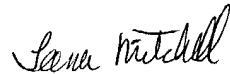
Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art is cited to show nasal cannula devices: 6,679,265; 6,561,193; 6,478,026; 5,975,077; 5,477,852; 5,269,296; 4,919,128; 4,915,105.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Teena Mitchell
Examiner
Art Unit 3743
December 5, 2004